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**CLAIMS**

1. Use of
(i) a nucleic acid construct comprising at least one hormone responsive element (HRE) and a transgene, said at least one HRE being not functionally linked to the transgene, and
(ii) a hormone-hormone receptor complex
for preparing an agent for gene transfer.

2. The use of claim 1, wherein the transgene is selected from the group consisting of genes encoding a blood clotting factor, hormone genes, hormone receptor genes, growth factors, enzyme genes, genes encoding cytokines or lymphokines, genes encoding inhibitor substances, genes encoding substances that function as drugs or vaccines, and antisense sequences.

3. The use of claim 2, wherein the transgene is a gene encoding a blood clotting factor and the agent is suitable for treating hemophilia.

4. The use of claim 3, wherein the blood clotting factor is a human blood clotting factor and preferably is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (vWF).

5. The use of any one of claims 1 to 4, wherein the nucleic acid construct comprises 1 to 20, preferably 3 to 10 HRE(s).

6. The use of any one of claims 1 to 5, wherein the at least one HRE is a steroid responsive element, preferably a progesterone responsive element (PRE).

7. The use of claim 4, wherein the HRE is a PRE and the blood clotting factor is factor IX, preferably the factor IX has a nucleotide sequence of 689 to 2071 of SEQ ID NO: 1.

8. The use of claim 5, wherein the HRE is a PRE and the blood clotting factor is factor VIII.

9. The use of any one of claims 6 to 8, wherein the PRE has the double stranded DNA sequence comprised of the DNA sequences of SEQ ID NOs: 3 and 4.

10. The use of any one of claims 1 to 9, wherein the construct further comprises functional DNA sequences selected from the group consisting of promoter sequences, enhancer sequences, silencer sequences, origin of replication sequences, integrational sequences, marker genes and switch sequences.

11. The use of claim 10, wherein the construct further comprises a tissue-specific promoter, preferably an α-antitrypsin promoter.

12. The use according to any one of claims 1 to 11, wherein the hormone-hormone-receptor complex is a steroid-steroid receptor complex.

13. The use of claim 12, wherein the molar ratio of HRE within the nucleic acid construct to hormone receptor is from 1:1 to 1:10, preferably 1:2 to 1:5, and/or the molar ratio of hormone to hormone receptor is at least 1000:1, preferably at least 10000:1.

14. The use of claim 12 or 13, wherein the receptor is a progesterone receptor and the steroid is progesterone or a progesterone derivative.

15. The use of claim 14, wherein the progesterone is natural micronized progesterone solubilized in a liphophilic matrix system and/or the progesterone receptor is hPR-A, hPR-B or comprises the nucleotide sequence of 557 to 933 SEQ ID NO:18.

16. A pharmaceutical composition comprising a nucleic acid construct comprising at least one HRE and a transgene as defined in claims 1 to 11 and/or a vector comprising said nucleic acid construct, said at least one HRE being coupled to a hormone-hormone receptor complex.

17. The pharmaceutical composition of claim 16, wherein the hormone-hormone receptor complex is as defined in claims 12 to 15.

18. The pharmaceutical composition of claim 16, wherein the transgene is a gene encoding a blood clotting factor.

19. The pharmaceutical composition of claim 18 wherein the blood clotting factor is factor IX.

20. The pharmaceutical composition of claim 18 wherein the blood clotting factor is factor VIII.

21. The pharmaceutical composition of any one of claims 18 to 20, which is suitable for gene transfer, preferably for treating hemophilia.

22. A nucleic acid construct comprising at least one HRE and a transgene being a gene encoding a blood clotting factor, wherein one of said at least one HREs is not functionally linked to the transgene.

23. The nucleic acid construct of claim 22, which is as defined in claims 4 to 11.

24. A vector comprising the nucleic acid construct of claim 22 or 23.

25. A transformed cell or transgenic organism comprising the nucleic acid construct as defined in claims 22 or 23 or the vector as defined in claim 24.

26. A composition of matter comprising
- the nucleic acid construct comprising at least one HRE and a transgene as defined in of claim 22 or 23, and/or
- a vector comprising said nucleic acid construct, said at least one HRE being coupled to a hormone-hormone receptor complex.

27. A method for preparing the composition of matter as defined in claim 26, which method comprises admixing the nucleic acid construct with the hormone receptor and the hormone.

28. A method for gene transfer which comprises administering the agent as defined in claims 1 to 15, or the pharmaceutical composition as defined in claims 16 to 20 to an organism or to a cellular system.

29. A method for delivering into an organism or into a cellular system a nucleic acid encoding a transgene to be expressed in the cells of the organism or the cells of the cellular system, which method comprises administering an agent as defined in claims 1 to 15 or a pharmaceutical composition as defined in claims 16 to 20 to the organism or to the cellular system so that the hormone in the composition interacts with the cell membrane and therewith enhances diffusion and transport of the nucleic acid that is coupled to the hormone-hormone receptor complex across the membrane and into the cell.

30. The method of claim 29, wherein a nucleic acid encoding human factor VIII or factor IX is delivered into the cell.

31. A method of treating blood clotting disorders comprising administering a therapeutically effective amount of the pharmaceutical composition of claim 18 to an organism or to a cellular system.

32. A method of treating hemophilia B, comprising administering a therapeutically effective amount of the pharmaceutical composition of claim 19 to an organism or to a cellular system.

33. A method of treating hemophilia A, comprising administering a therapeutically effective amount of the pharmaceutical composition of claim 20 to an organism or to a cellular system.

34. Use of
(i) a nucleic acid construct comprising at least one hormone responsive element (HRE) and a transgene wherein the transgene is a gene encoding a blood clotting factor and the at least one HRE is functionally linked to the transgene, and
(ii) a hormone-hormone receptor complex
for preparing an agent for treating heomphilia.

35. The of claim 34, wherein the blood clotting factor is a human blood clotting factor and preferably is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (vWF).

36. The use of claims 34 or 35, wherein the nucleic acid construct comprises 1 to 20, preferably 3 to 10 HRE(s).

37. The use of claim 34 to 36, wherein the at least one HRE is a steroid responsive element, preferably a progesterone responsive element (PRE).

38. The use of claim 35, wherein the HRE is a PRE and the blood clotting factor is factor IX, preferably the factor IX has a nucleotide sequence of 689 to 2071 of SEQ ID NO: 1.

39. The use of claim 35, wherein the HRE is a PRE and the blood clotting factor is factor VIII.

40. The use of claim 37 to 39, wherein the PRE has the double stranded DNA sequence comprised of the DNA sequences of SEQ ID NOs: 3 and 4.

41. The use of claims 34 to 40, wherein the construct further comprises functional DNA sequences selected from the group consisting of promoter sequences, enhancer sequences, silencer sequences, origin of replication sequences, integrational sequences, marker genes and switch sequences.

42. The use of claim 41, wherein the construct further comprises a tissue-specific promoter, preferably an α-antitrypsin promoter.

43. The use according to any one of claims 34 to 42, wherein the hormone-hormone receptor is a steroid-steroid receptor complex.

44. The use of claim 43, wherein the molar ratio of HRE within the nucleic acid construct to hormone receptor is from 1:1 to 1:10, preferably 1:2 to 1:5, and/or the molar ratio of hormone to hormone receptor is at least 1000:1, preferably at least 10000:1.

45. The use of claim 43 or 44, wherein the receptor is a progesterone receptor and the steroid is progesterone or a progesterone derivative.

46. The use of claim 45, wherein the progesterone is natural micronized progesterone solubilized in a liphophilic matrix system and/or the

progesterone receptor is hPR-A, hPR-B or comprises the nucleotide sequence of 557 to 933 SEQ ID NO:18.

47. A method for gene transfer which comprises administering the agent as defined in claims 34 to 46 to an organism or to a cellular system.

48. A method for delivering into an organism or into a cellular system a nucleic acid encoding a transgene to be expressed in the cells of the organism or the cells of the cellular system, which method comprises administering an agent as defined in claims 34 to 46 to the organism or to the cellular system so that the hormone in the composition interacts with the cell membrane and therewith enhances diffusion and transport of the nucleic acid that is coupled to the hormone-hormone receptor complex across the membrane and into the cell.

49. The method of claim 48, wherein a nucleic acid encoding human factor VIII or factor IX is delivered into the cell.